REMARKS

Claims 1, 3-9 and 12-18 should be pending and under consideration in the application. The Office Action acknowledges the pendancy of claim 1 and 3-9; however, no such acknowledgement is provided as to claims 12-18, introduced in the last Amendment. Nor were claims 12-18 made the subject of any rejection. At a minimum, withdrawal of the present Office Action and issuance of a new Office Action addressing all submitted claims is in order. It is believed, however, that such action is unnecessary, as it is believed that the present response will point out with clarity that claims 1, 3-9 and 12-18 should be passed to allowance. Prompt such action is thus requested.

A single rejection is stated the Office Action, beginning at page 3, second full paragraph. It is directed to claims 1 and 3-9, and is made under the provisions of 35 U.S.C. 103. The reference combination used in the rejection is "Douglas US Patent 6,090,128 in view of Gregory US Patent 5,990,379". This rejection is in error for the reasons discussed in sections I-IV below.

I. The Independent Claims in the Rejection

There are two independent claims in the rejection, claims 1 and 3. Independent claim 1 is directed to a stent graft comprising at least one stent having a proximal end and a distal end and having a lumen extending therethrough between the proximal and distal ends. The stent graft includes a covering of collagen having an isolated extracellular matrix layer that becomes remodeled by host tissue secured to the at least one stent and extending therealong between the proximal and distal ends. As claimed, the covering is a sleeve that initially has a length about equal to twice the length of the at least one stent. A first portion of the sleeve extends along and complements inside surface of the at least one stent, and a second portion of the sleeve is folded back over a proximal end of the at least one stent and then along an outside surface of the at least one stent to the distal end thereof. The first portion and the second portion of the sleeve are secured to at least the distal end of the at least one stent.

Independent claim 3 is directed to a stent graft comprising at least one stent having a proximal end and a distal end and having a lumen extending therethrough between the proximal and distal ends. The stent graft includes a covering of collagen having an isolated extracellular matrix layer that becomes remodeled by host tissue secured to the at least one stent and extending therealong between the proximal and distal ends, wherein the covering is a sleeve that initially has a length about equal to twice the length of the at least one stent. A first portion of the sleeve extends along and complements inside surface of the at least one stent, and a second portion of the sleeve is folded back over a proximal end of the at least one stent and then along an outside surface of the at least one stent to the distal end thereof. The stent graft further comprises a plurality of stents connected together to form a stent frame with lumens of the respective stents coaligned to form a common continuous lumen extending from a distal stent frame end to a proximal stent frame end, and the covering extending therealong between the proximal and distal stent frame ends.

II. The Applicable Law

When rejecting claims under 35 U.S.C. § 103, "the Examiner bears the burden of establishing a *prima facie* case of obviousness based upon the prior art." In re Fritch, 23 U.S.P.Q. 2d 1780, 1783 (Fed. Cir. 1992).[1] To establish a *prima facie* case of obviousness, the Examiner must provide objective evidence 1) of some suggestion or motivation to combine or modify one or more prior art references,[2] 2) that the suggested combination or modification has a reasonable expectation of success,[3] and 3) that the prior art reference or references, when combined, suggest or teach all of applicant's claim limitations. MPEP § 2143. As held by the Federal Circuit, "[t]hese findings or evidence

[1] Citing In re Piasecki and Meyers, 223 U.S.P.Q. 785, 787-88 (Fed. Cir. 1984).

[2] This motivation must be found in the references or within the body of knowledge available to a person of ordinary skill in the art at the time applicant's invention was conceived. See, MPEP § 2142.

[3] "Both the suggestion and the reasonable expectation of success must be founded in the prior art, not in the applicant's disclosure." In re Vaeck, 20 U.S.P.Q. 2d 1438, 1442 (Fed. Cir. 1991) (citing In re Dow Chemical Co., 5 U.S.P.Q. 2d 1529, 1531 (Fed. Cir. 1988)).

must be specific, clear, and particular." In re Lee, 61 U.S.P.Q. 2d 1430, 1433-34 (Fed. Cir. 2002). "Broad conclusory statements regarding the teaching of multiple references, standing alone, are not [considered sufficient] 'evidence'[4]" to support a finding of *prima facie* obviousness. In re Dembiczak, 50 U.S.P.Q. 2d 1614, 1617 (Fed. Cir. 1999); See also, Ex Parte Levengood, 28 U.S.P.Q. 2d 1300, 1301 (Bd. Pat. App. & Int. 1993).

Obviousness determinations must be performed without "entry into the 'tempting but forbidden zone of hindsight.'" Dembiczak, 50 U.S.P.Q. 2d at 1616 (Fed. Cir. 1999).[5] More specifically, in Dembiczak, the Federal Circuit offered the following guidance:

> [m]easuring a claimed invention against the standard established by section 103 requires the oft-difficult but critical step of casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field.[6] . . .

Dembiczak, 50 U.S.P.A. 2d at 1617.[7] The best protection against the use of hindsight is a rigorous application of the motivation to combine criterion, which results in most *prima facie* obviousness determinations hinging on an objective finding of some motivation or suggestion to combine or modify one or more prior art references. See, Dembiczak, 50 U.S.P.Q. 2d at 1617; In re Roufett, 47 U.S.P.Q. 2d 1453, 1457-58 (Fed. Cir. 1998).

In the event the Examiner establishes a *prima facie* case of obviousness, applicants may submit rebuttal evidence to prove that the claim or claims are nonobvious. After rebuttal evidence is submitted, "[r]egardless of whether the *prima facie* case would have been characterized as strong or weak, the examiner must consider all of the

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[4] E.g., McElmurry v. Arkansas Power & Light Co., 995 F.2d 1576, 1578, 27 U.S.P.Q. 2d 1129, 1131 (Fed. Cir. 1993) ("Mere denials and conclusory statements, however, are not sufficient to establish a genuine issue of material fact.") [citation omitted].

[5] Quoting Loctite Corp. v. Ultraseal Ltd., 228 U.S.P.Q. 90, 98 (Fed. Cir. 1998) (overruled on other grounds).

[6] [citation omitted].

[7] Citing C.R. Bard, Inc. v. M3 Sys., Inc., 48 U.S.P.Q. 2d 1225, 1232 (Fed. Cir. 1998) (describing "teaching or suggestion or motivation [to combine]" as an "essential evidentiary component of an obviousness holding.")).

evidence anew." In re Piasecki and Meyers, 223 U.S.P.Q. 785, 788 (Fed. Cir. 1984). When evaluating rebuttal evidence, the Examiner must compare the claimed invention as a whole against the prior art references, rather than comparing components of the claimed invention to the prior art.[8] Additionally, in evaluating the obviousness of a claimed invention, the Examiner must also consider "objective evidence or secondary considerations." MPEP § 2141. For example, advantages directly flowing from the claimed invention are proper support for finding nonobviousness. Preemption Devices, Inc. v. Minn. Mining and Mfg. Co., 221 U.S.P.Q. 841, 844 (Fed. Cir. 1984) (citing Graham et al. v. John Deere Co. of Kan. City, 148 U.S.P.Q. 459 (U.S. 1966)).

III. Analysis Of The Rejected Claims And References

1. Claims 1 and 3-9 are Nonobvious Under 35 U.S.C. § 103 (a) Over Douglas (U.S. Pat. No. 6,090,128) in View of Gregory (U.S. Pat. No. 5,990,379).

The stated rejection of claims 1 and 3-9 over the combination of Douglas in view of Gregory fails to establish a *prima facie* case of obviousness. Such a case requires that an Examiner, among other things, provide objective evidence that when combined, the references relied upon suggest or teach all of Applicants' claim limitations. MPEP § 2143. These findings or evidence must be specific, clear and particular. Lee, 61 U.S.P.Q. 2d at 1433-34. Broad conclusory statements regarding the teaching of multiple references are not sufficient. Dembiczak, 50 U.S.P.Q. 2d at 1617. The rejection fails to comply with these standards and is thus improper.

In making this rejection, the Action acknowledges that the primary reference, Douglas, "does not disclose a sleeve made of SIS". Page 3, third line from the bottom.

[8] "In its argument that the invention here is but making integral what had earlier been made in four bolted pieces, Nortron seeks to limit the focus of inquiry to a structural difference from the prior art and then to show that that difference alone would have been obvious. That effort is not proper under the statute, which requires that an invention be considered 'as a whole' . . . ." Carl Schenck, A.G. v. Nortron Corp., 218 U.S.P.Q. 698, 700 (Fed. Cir. 1983).

After referencing the secondary Gregory reference, the Action bases this rejection upon the assertion that:

> It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the material property of the Douglas reference with the SIS sleeve of the Gregory reference in order to inhibit the migration of smooth muscle cells in the treated area.

However, the Gregory reference does not teach the use of a SIS (small intestinal submucosa) sleeve. Instead, the Gregory reference teaches the use of an elastin-based sleeve and never mentions small intestinal submucosa. On this point, it is noted that **dependent claims 8-9 require the presence of "small intestine submucosa" in the sleeve.** Thus, the references do not teach all of the elements of these claims. Further, independent claims 1 and 3 require the presence of **"a covering of collagen having an isolated extracellular matrix layer that becomes remodeled by host tissue".** The rejection relies upon an assertion that the Gregory reference teaches small intestinal submucosa as a covering material in order to meet this limitation. However, as noted above, the Gregory reference does not teach anything about small intestine submucosa. Accordingly, for this reason alone, this rejection is unsupported as to claims 1 and 3 and all claims dependent thereon, encompassing claims 1 and 3-9.

Consistently, claims 12-18 submitted with the last Reply require the presence of **"a covering of collagen having an isolated extracellular matrix layer that becomes remodeled by host tissue"**, and claims 17-18 of this set require the presence of **"small intestine submucosa"**. For at least those reasons discussed above in connection with claims 1 and 3-9, it is submitted that claims 12-18 are also not taught or suggested by the combination of Douglas and Gregory set forth in the Office Action. Moreover, claims 12-18 are directed to a stent graft device having "a stent frame defining only a single lumen extending from a first end of said stent graft device to a second end of said stent graft device". The primary Douglas reference, which is relied upon to teach frame/covering attachment aspects in the rejection of claims 1 and 3-9, defines multiple

lumens from one end to the other, directly contrasted to claims 12-18. Accordingly, allowance of claims 12-18 is solicited.

IV. Response to Examiner's Remarks at Page 2 of the Office Action

In the prior response, Applicants pointed out that the Examiner's characterization of the Gregory reference as disclosing a small intestine submucosa (SIS) sleeve was incorrect, because Gregory never discloses this material. Given this, and given the fact that it was the supposed Gregory teaching of SIS that was relied upon by the Examiner to meet the sleeve covering aspects of the claims, it was believed that it would be clear that the rejection made was not properly supported. In the responsive comments at page 2 of the Office Action, the Examiner reasserts that the proposed combination of references establishes a *prima facie* case of obviousness. In doing so, the Examiner posits that "Regarding the Gregory reference, the Examiner wants to clarify that the independent claims don't disclose the use of SIS". However, it is submitted that this remark does not address the issues under consideration. As a first point, in the previous Action, the Examiner had relied upon the supposed SIS teaching of Gregory to meet the covering limitations of the independent claims. The independent claims require "**a covering of collagen having an isolated extracellular matrix layer that becomes remodeled by host tissue**". The Gregory reference fails to teach this feature, either by identifying SIS, or otherwise. There is absolutely no teaching in the Gregory reference as to isolated extracellular matrix layers that remodel. As noted in the Declaration of Dr. Michael Hiles submitted with the last reply, remodelable materials are understood to possess properties that balance degradation of the implanted material with new native tissue ingrowth to replace the implanted material as it is degraded. There is absolutely no teaching of such features in any of the disclosures in Gregory. As a second point, claims 8-9, which were included in the rejection, do require the use of a covering material comprising "**small intestine submucosa**". It is thus difficult to understand how the failure of Gregory to disclose small intestine submucosa can continue to be disregarded in rejecting the claims over Douglas in view of Gregory. Moreover, the remarks at page

2 of the Office Action cite col. 5, lines 36-48 of Gregory for asserted teachings with regard to potential covering materials. The passages set forth at this location only serve to confirm the points above: (1) Gregory does not teach the use of remodelable materials as claimed in all claims; and (2) Gregory does not teach the use of small intestine submucosa as claimed in claims 8-9 (and submitted claims 17-18). Consequently, the rejection is in error and should be withdrawn.

Further, in the final paragraph at page 2 of the Office Action, the Examiner addresses the Declaration of Dr. Michael Hiles previously submitted. As asserted basis for finding the Declaration as insufficient, the Examiner states that "the Applicant's representative has not discloses *[sic]* factual evidence and has only discloses *[sic]* an opinion. While an opinion as to a legal conclusion is not entitled to any weight the underlying basis for the opinion may be persuasive. In re Chilowsky, 306 F.2d 908, 134 USPQ 515 (CCPA 1962)." If, after considering this response, the Examiner continues to believe that the Declaration only states an opinion as to a legal conclusion, it is requested that the Examiner point out the specific passages thought to be legal conclusion.

In fact, the Declaration provides discussion of technical aspects of the invention, not legal conclusions. These technical aspects amplify the legal conclusion of nonobviousness. In particular, as noted by Dr. Hiles:

> The use of such remodelable materials in stent grafts with the claimed covering features presents significant advantages in device manufacture and use. When the ends of the claimed covering material are attached at the stent's distal end as in independent claim 1, the sutures or other attachment means responsible for securing the loose sleeve ends will not need to be placed somewhere along the middle of the stent(s). This means that any attachments along the central portion of the device can be eliminated or minimized. This can be beneficial because any foreign materials (such as sutures) that interrupt the remodelable material field covering the stent(s) can initiate a foreign body response upon implantation in a patient. This foreign body response could have an adverse impact upon the balanced graft resorption and tissue ingrowth in the remodeling process. Further, where multiple connected stents are used in the stent graft structure as in independent claim 3, the sleeve covering

extending over all of the connected stents provides the ability to encompass and cover the connected portions of the multiple stents, including any materials such as filaments or other structures used in the connection. Such filaments or other structures can also present foreign bodies that could initiate a response that interferes with the desired, balanced remodeling function of the covering as it contacts bodily lumen surfaces. This foreign body response can deleteriously affect or detract from the healing and remodeling process that is induced by the claimed remodelable covering material. The ability to avoid or minimize foreign body material at the stent's midpoint as enabled by the present invention can lead to more effective tissue ingrowth and remodeling. In addition, in the case of a multiple-stent graft structure (see independent claim 3), the sleeve

This declaration by Dr. Hiles is confined to technical aspects of the claimed invention, and advantages that can be provided thereby. Accordingly, it cannot be dismissed as legal conclusion. Further, if the Examiner has reason to doubt the accuracy of the technical aspects averred in the Declaration, it is requested that the Examiner provide sound technical reasoning supporting the same.

The technical aspects pointed out in Dr. Hiles' Declaration must be taken into account when considering the claimed invention as a whole. The use of a remodelable covering in the claimed configurations provides particular advantages to the stent graft device that are not disclosed *or even hinted at* in the references relied upon. Although not believed to be necessary to find the claimed invention nonobvious, these advantages provide further support to the patentability of the claims.

Conclusion

Claims 1 and 3-9 are not obvious over Douglas in view of Gregory, nor are previously submitted claims 12-18. Withdrawal of the rejection of claims 1 and 3-9 and passage of this application to allowance with claims 1, 3-9 and 12-18 are solicited.

Respectfully Submitted,

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